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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,222	09/08/2003	Morton M. Mower	302527US78	1067
22850	7590	02/18/2010	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				KAHELIN, MICHAEL WILLIAM
ART UNIT		PAPER NUMBER		
3762				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/656,222	MOWER, MORTON M.
	Examiner	Art Unit
	MICHAEL KAHELIN	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 January 2010.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3,20,27,28,34,67 and 69-71 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,3,20,27,28,34,67 and 69-71 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>20100121</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/21/2010 has been entered.
2. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Amendment

3. The declaration under 37 CFR 1.132 filed 1/21/2010 is insufficient to overcome the rejection of claims 1, 3, 20, 27, 28, 34, 67, and 69-71 under 35 U.S.C. §§ 102 and/or 103 based upon Yu et al. (US 2003/0105496, hereinafter "Yu") as set forth in the last Office action. In regards to items 10-13, it appears that there is a lacking nexus between the secondary evidence and the claimed invention. See MPEP § 716.01(b). The declaration is drawn to asserted issues with pacing of the left ventricle only for intra-chamber synchronization, but the claims recite positioning signaling electrodes to deliver stimulation to only a left ventricle. In other words, the claims do not require pacing only the left ventricle, but only first and second electrodes positioned such that they are capable of pacing only the left ventricle; the claims permitting additional electrodes that pace other chambers.

4. In regards to item 12, Declarant asserts that the modification of Yu's electrode 144 to comprise a helical attachment means is not *prima facie* obvious because other methods are known to access the left ventricle ("the most straightforward method of pacing the left ventricle consists of pacing through a retrograde catheter"). However, the fact that other approaches may have also been obvious does not render the proposed modification unobvious. Further, it is unclear which recognized "secondary consideration" this position is meant to address. Declarant does not argue inoperability of the prior art, and in fact notes that an electrode with such septal placement is capable

of delivering stimulation to only a left ventricle. See item 13. Regardless of whether thrombosis complications may or may not exist with lead placed through a retrograde catheter placed in the left ventricle, this is not the modification of Yu that the examiner proposes. The modification is a septal placement from the right ventricle, as shown by, e.g., Altman (US 5,551,427, cited in paragraph 11 of the previous Office Action).

5. In regards to item 13, Declarant takes the position that pacing the right ventricular septum *is* pacing *only* the left ventricle because this surface is functionally left ventricle. However, it is again unclear what "secondary consideration" of non-obviousness this is meant to address. Yu's electrode 14 appears to be positioned in the middle of the interventricular septum (Fig. 3), and thus "preferentially stimulate[s] left ventricular myocardium and does not immediately affect the right ventricle" per Declarant's statement. Discovery that right ventricular endocardium is functionally left ventricle appears to be an inherent property of the heart. Yu appears to provide disclosure of the claim limitations based on his stimulation of the same location, regardless of whether he recognized this inherent property at the time of invention.

Information Disclosure Statement

6. The information disclosure statement filed 1/21/2010 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the cited reference lacks a publication date. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for

purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 20, 27, 28, 34, 67, and 69-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner was unable to find support in the originally-filed application for the combination of elements including positioning electrodes to deliver stimulation to “only a left ventricle.” Figure 4 shows an additional electrode in the right atrium, and the Examiner was further unable to find a basis for the septal stimulation being limited to the left ventricle (*i.e.*, the disclosure does not indicate that the septal electrode *does not* also stimulate the right ventricle). Further, the lack of additional electrodes in the figure is not a basis for exclusion. Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the

original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 3, 20, 27, 28, 34, 67, and 69-71 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Yu et al. (US 2003/0105496, hereinafter “Yu”), or in the alternative under 35 U.S.C. 103(a) as over Yu.

11. In regards to claims 1, 27, 34, 67, and 71, Yu discloses providing a first electrode to the left ventricle coronary vein, a second electrode to the septum, and performing intrachamber resynchronization with the electrodes (pars. 0013, 0027 and 0035). As Applicant apparently considers the septal electrode of Figure 4 to deliver stimulation to

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only the left ventricle, Yu's septal electrode 44 likewise delivers stimulation to only a left ventricle. The claim language does not require a lack of other electrodes, but another reasonable interpretation is that the two claimed signaling electrodes deliver stimulation to *only* the left ventricle, while other electrodes can be present to stimulate other areas. As such, Yu's signaling electrodes 144 and 142 deliver stimulation to only a left ventricle. In the alternative, Yu discloses the essential features of the claimed invention except for explicitly disclosing that the septal electrode 144 delivers stimulation to only the left ventricle. However, it is well known in the pacing arts to provide septal electrodes with screw-in tips that provide stimulation to only the left ventricle to provide the predictable result of reaching the desired chamber for pacing therapy without the accompanying thrombosis complications. Therefore, it would have been obvious to one having ordinary skill in the art to provide Yu's invention with a septal electrode provides stimulation to only the left ventricle to provide the predictable result of reaching the desired chamber for pacing therapy without the accompanying thrombosis complications.

12. In regards to claims 3 and 69, Yu discloses receiving signals from multiple left ventricular sites (par. 0028).

13. In regards to claims 20 and 70, the electrodes are endocardial electrodes (Fig. 3).

14. In regards to claim 28, delivering includes providing a lead through the SVC, RA, ostium of the coronary sinus, and coronary vein (par. 0027 and Fig. 3).

Response to Arguments

15. Applicant's arguments filed 1/21/2010 have been fully considered but they are not persuasive. Applicant argued that paragraph 057 provides written description support for the limitations drawn to delivering stimulation to "only a left ventricle." However, this paragraph appears to refer to a prior art approach and does not necessarily refer to the disclosed embodiment. Furthermore, the passage in the disclosure referring to "pacing only in the left ventricle" does not provide disclosure that the electrode delivered to the right ventricular wall delivers stimulation to "only a left ventricle," as claimed. In other words, regardless of whether paragraph 057 discloses left-ventricle-only pacing generally, the examiner maintains that this does not provide written description for the electrode placement of Figure 4 specifically providing stimulation to "only a left ventricle" (*i.e.*, does not provide any stimulation to the right ventricle).

16. Applicant further argued that Yu fails to render the claimed subject matter obvious in light of the declaration filed 1/21/2010. It is noted that Applicant did not address the basis of rejection in view of Yu under 35 USC § 102. The claims were rejected under § 102 and additionally and alternatively under § 103 due to the scope of the claim limitations drawn to positioning an electrode to deliver stimulation to "only a left ventricle" that allow for alternative interpretations. One interpretation of this limitation is that Yu's electrode necessarily delivers stimulation to only a left ventricle (even though it is clearly shown as being placed in the right ventricle) because Applicant considers the septal electrode shown in, *e.g.*, Fig. 4 of Applicant's disclosure to deliver

stimulation to “only a left ventricle” and makes a similar statement in item 13 of the declaration of 1/21/2010 (“the surface of the right side of the septum is functionally left ventricle”). This rationale relies on the position that Yu also necessarily delivers stimulation to “only a left ventricle” based on the similar area of electrode placement (see element 144 in Figure 3). The alternative rejection under § 103 relies on the position that, even if positioning a septal electrode to deliver stimulation to “only a left ventricle” indispensably requires a helical structure as shown in, e.g., Fig. 4 of Applicant’s disclosure, this feature is well known in the art and it would have been obvious to provide Yu’s element 14 with such an attachment means. Based on electrode 144 being a left ventricular electrode, “intrachamber resynchronization” is performed in concert with electrode 140 per, e.g., paragraphs 0013, 0027, 0035, and 0047.

Conclusion

17. This is an RCE of applicant's previous identical claims. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762